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| 10/804,592 | 03/19/2004 | William Galbraith | 80154 | 9558 |
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| DAVID W. HIGHER, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880 | | | EXAMINER YU, MELANIE J. | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,592

Applicant(s)

GALBRAITH, WILLIAM

Examiner

Melanie Yu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 24-31, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 24-31, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 18 August 2006 has been entered.

Withdrawn Rejections

2. Previous rejections under 35 USC 102(b) and 35 USC 103(a) have been withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 6 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sjöholm et al. (US 4,061,466).

Sjöholm et al. teach an apparatus comprising an insoluble support (cross linked agarose or microparticles) having a ligand of bromosulphophthalein attached thereto (bromosulphophthalein is bromosulphophthalein) without being exposed to albumin (particles are capable of absorbing albumin, but are not present when bromosulphophthalein is attached to the particle, example 9, col. 9, lines 34-43).

With respect to claims 2, 4 and 6, Sjöholm et al. teach the support contained within a container (particles are in a container, col. 4, lines 60-67) and the container being a bottle (beaker is a bottle, col. 8, lines 23-26). Sjöholm et al. also teach a the support being a matrix (polyethylene glycol is a matrix and entrapped in the particles, col. 9, lines 39-43).

4. Claims 1-6, 24-27 is rejected under 35 U.S.C. 102(b) as being anticipated by Grahnén et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580).

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Grahnén et al. teach an apparatus comprising an insoluble support (sepharose column) having a ligand consisting of bromosulphophthalein attached thereto, without being exposed to albumin (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*).

With respect to claims 2-6 and 25-27, Grahnén et al. teach that the insoluble support is contained in and supported in a column (affinity column with bromosulphophthalein as a ligand, pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*; and pg. 575, right column, last 2 paragraphs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper et al. (US 2002/0127739) in view of Grahnén et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharex, 1977, Eur. J. Biochem., Issue 80, pages 573-580).

Pieper et al. teach a column comprising one or more additional supports capable of binding one or more non-albumin proteins (par. 0067), wherein the supports include one or more supports capable of binding IgA and IgG (different matrices carrying different binding agents to remove proteins from a sample is provided at par. 0067; sample proteins of IgG and IgA are non-albumin and are listed at pg. 9, Table 1). Pieper et al. fail to teach a ligand of bromosulphophthalein.

Grahnén et al. teach a ligand comprising bromosulphophthalein attached to an insoluble support a column (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*), in order to bind albumin.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the column of Pieper et al., a binding agent of bromosulphophthalein as taught by Grahnén et al., in order to provide a detectable ligand specific to albumin, which strongly influences the affinity of albumin to the ligand and provides detectable properties upon binding which ensures removal.

Regarding claims 30 and 31, Pieper et al. teach a support bindable to IgA (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgA has a separate column body par. 0102) and a support bindable to IgG (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgG has a separate column body par. 0102) wherein the support comprises protein A and G cartridge (a column comprising protein G and A bind IgG; see under Table 1).

6. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahnén et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580), as applied to claims 1 and 24, in view of Matzinger et al. (US 6,680,176) further in view of Shi et al. (US 5,919,626).

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Grahnén et al. teach a ligand comprising bromosulfophthalein attached to an insoluble support, but fails to teach the ligand attached via an epoxy linkage.

Ebersole et al. teach a hydroxyl group of a molecule covalently bound to a substrate through an epoxy linkage (matrix is epoxy activated and therefore molecules bind with the matrix through the activated epoxy, which would be an epoxy linkage, col. 15, line 53-col. 16, line 16), in order to provide a covalent bond between the ligand and the substrate.

Shi et al. teach that an epoxy linkage to a receptor agent is beneficial because the linkages are stable to heat, high salt and elevated temperatures (col. 9, lines 1-14).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Grahnén et al., to the hydroxy group on the ligand to the substrate via an epoxy linkage as taught by Ebersole et al., in order to provide linkages that are stable in heat and elevated temperatures as taught by Shi et al.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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8. Claims 1-6 and 24-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 24-31 of copending Application No. 10/922,560 in view of Grahnén et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580). Application '560 recites the same limitations as instant claims 2-6 and 25-31 (claims 2-6 and 25-31), and with respect to instant claims 1 and 24, application '560, recites an insoluble support having a ligand attached thereto, wherein the ligand comprises bromosulphophthalein (claims 1 and 24). Claims 1 and 24 of application '560 fail to specifically recite the ligand attached without being exposed to albumin and the ligand consisting of bromosulphophthalein. Grahnén et al. teach a ligand consisting of bromosulphophthalein being attached to a support without being exposed to albumin (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*), in order to prepare an affinity chromatography support. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus/kits of application '560, bromosulphophthalein attached directly to the support without exposure to albumin, in order to provide an affinity chromatography support for bromosulphophthalein.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 26-31 and 50-51 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the ligand be bound without being exposed to albumin and the ligand "consisting of" bromosulphophthalein.

Conclusion

No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melanie Yu
Patent Examiner
Art Unit 1641



LONG V. LE 6/27/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600